PUMA BIOTECHNOLOGY, INC.
Form 8-K
December 18, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 18, 2015

PUMA BIOTECHNOLOGY, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-35703**	**77-0683487**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

10880 Wilshire Boulevard, Suite 2150

Los Angeles, California 90024

(Address of principal executive offices) (Zip Code)

(424) 248-6500

(Registrant s telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On December 18, 2015, Puma Biotechnology, Inc. (the Company) announced that it has expanded the third cohort from its Phase II clinical trial of its lead drug candidate PB272 (neratinib) as a single agent in patients with solid tumors who have an activating HER2 mutation (basket trial). The cohort that has been expanded is the cohort that includes patients with metastatic biliary duct (bile duct) cancer and whose tumors have a HER2 mutation.

The Phase II basket trial, which was initiated in October 2013, is an open-label, multicenter, multinational study to evaluate the safety and efficacy of PB272 administered daily to patients who have solid tumors with activating (driver) ERBB mutations including EGFR, HER2 and HER3. The cohorts (baskets) included in the study are: (1) bladder/urinary tract cancer; (2) breast cancers; (3) colorectal cancer; (4) endometrial cancer; (5) gastric/esophageal cancer; (6) ovarian cancer; (7) all other solid tumors with a HER2 mutation; (8) EGFR mutated and/or amplified primary brain cancer; and (9) solid tumors with a HER3 mutation. The biliary duct cancer patients initially entered the study in the other solid tumors with a HER2 mutation basket and due to the preliminary activity seen in the trial the Company has expanded the basket, as per the protocol for the trial. The expanded HER2 mutant metastatic biliary duct basket will now enroll a total of 18 patients.

The Company anticipates expanding additional cohorts from the basket trial during 2016.

Forward-Looking Statements:

This Current Report on Form 8-K contains forward-looking statements, including statements regarding anticipated timing for various clinical trials. All forward-looking statements included in this Current Report on Form 8-K involve risks and uncertainties that could cause the Company s actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, which include, but are not limited to, the fact that the Company has no product revenue and no products approved for marketing, the Company s dependence on PB272, which is still under development and may never receive regulatory approval, the challenges associated with conducting and enrolling clinical trials, the risk that the results of clinical trials may not support the Company s drug candidate claims, even if approved, the risk that physicians and patients may not accept or use the Company s products, the Company s reliance on third parties to conduct its clinical trials and to formulate and manufacture its drug candidates, the Company s dependence on licensed intellectual property, and the other risk factors disclosed in the Company s Annual Report on Form 10-K for the year ended December 31, 2014 and in subsequent periodic and current reports filed by the Company with the Securities and Exchange Commission from time to time. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to update these forward-looking statements, except as required by law.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PUMA BIOTECHNOLOGY, INC.

Date: December 18, 2015

By: /s/ Alan H. Auerbach
Alan H. Auerbach
President and Chief Executive Officer